

K113153

NOV 28 2011

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92(c).

The assigned 510(k) number is: K113153.

1. Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen,
518057, P. R. China

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Contact Person:

Tan Chuanbin

Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,
Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: October 10th, 2011

2. Device Name:

DP-20 Digital Ultrasonic Diagnostic Imaging System (new added sub-model)

DP-30 Digital Ultrasonic Diagnostic Imaging System (new added sub-model)

Classification

Regulatory Class: II

21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

3. Device Description:

The DP-20 and DP-30 Digital Ultrasonic Diagnostic Imaging System are general purpose, portable/mobile (with mobile ultrasound trolley), software controlled, ultrasonic diagnostic systems. Its function is to acquire and display ultrasound data in B-Mode,

M-Mode, or their combined mode B+M Mode. The systems are Track 1 device that employs an array of transducers including linear array and convex array. The frequency range of DP-20 is approximately 2.0 MHz to 10.0 MHz and that of DP-30 is approximately 2.0 MHz to 12.0 MHz.

4. Intended Use:

The DP-20 and DP-30 Digital Ultrasonic Diagnostic Imaging System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, intraoperative(abdominal, thoracic, and vascular), pediatric, small organ(breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), cardiac(adult, pediatric), peripheral vascular and urology exams.

5. Comparison with Predicate Device:

DP-20 and DP-30 Digital Ultrasonic Diagnostic Imaging System is comparable with and substantially equivalent to the Mindray DP-6900 Digital Ultrasonic Diagnostic Imaging System (K090912), M5 Diagnostic Ultrasound System(K102991) and M7 Diagnostic Ultrasound System(K103677). They have the same technological characteristics, are comparable in key safety and effectiveness features, and have the same intended uses and basic operating modes as the predicate device.

6. Non-clinical Tests:

DP-20 and DP-30 Digital Ultrasonic Diagnostic Imaging System has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical safety standards. This device has been designed to meet the following standards: UD 2, IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-2-37, IEC 60601-1-4, ISO 10993-1 and IEC 62304.

Conclusion:

Intended uses and other key features are consistent with traditional clinical practices, FDA guidelines and established methods of patient examination. The design, development and quality process of the manufacturer confirms with 21 CFR 820, ISO 9001 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards. Therefore, the DP-20 and DP-30 Digital Ultrasonic Diagnostic Imaging System is substantially equivalent with respect to safety and effectiveness to devices



DEC - 6 2011

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
% Ms. Susan D. Goldstein-Falk
Official Correspondent
MDI Consultants, Inc.
55 Northern Blvd, Suite 200
GREAT NECK NY 11021

Re: K113153

Trade/Device Name: DP-20, DP-30 Digital Ultrasonic Diagnostic Imaging System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: October 10, 2011
Received: October 25, 2011

Dear Ms. Goldstein-Falk:

This letter corrects our substantially equivalent letter of November 28, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the DP-20, DP-30 Digital Ultrasonic Diagnostic Imaging System, as described in your premarket notification:

Transducer Model Number

35C20EA
35C50EB
65C15EA

65EC10EB
65EL60EA
75L38EB

75L53EA
75LT38EA
35C20EA

35C50EA
65C15EA
65EC10EA
65EL60EA

65EB10EA
65EC10ED
75L38EA
75L53EA

75LT38EA
10L24EA

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (301) 796-6881.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mary S. Pastel", followed by the word "for" in a cursive script.

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indications for Use510(k) Number (if known): K613153

Device Name: DP-20, DP-30 Digital Ultrasonic Diagnostic Imaging System


Indications for Use:

The DP-20 and DP-30 Digital Ultrasonic Diagnostic Imaging System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, intraoperative (abdominal, thoracic, and vascular), pediatric, small organ (breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), cardiac (adult, pediatric), peripheral vascular and urology.

Prescription Use X AND/OR Over-the-Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


(Susan D. Falk)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

SIC: K613153

0029

Diagnostic Ultrasound Indications for Use Form

System

x

Transducer

Model:

DP-20

SIO(k) Number(s)

K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	N	N					N	Note 1, Note 2
Abdominal	N	N					N	Note 1, Note 2
Intraoperative (specify)*	N	N					N	Note 2
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N					N	Note 1, Note 2
Small organ (specify)**	N	N					N	Note 2
Neonatal Cephalic	N	N					N	Note 2
Adult Cephalic	N	N					N	Note 2
Trans-rectal	N	N					N	Note 2
Trans-vaginal	N	N					N	Note 2
Trans-urethral								
Trans-esoph (non-Card)								
Musculo-skeletal Conventional	N	N					N	Note 1, Note 2
Musculo-skeletal Superficial	N	N					N	Note 2
Intravascular								
Cardiac Adult	N	N					N	Note 2
Cardiac Pediatric	N	N					N	Note 2
Intravascular (Cardiac)								
Trans-esoph (Cardiac)								
Intra-Cardiac								
Peripheral Vascular	N	N					N	Note 2
Other (specify)***	N	N					N	Note 1, Note 2

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The system does not use contrast agents.

Note 2: Biopsy Guidance.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRE, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR
§91.109)

[Signature]
 (Division Sign-Off)
 Division of Radiological Devices
 Office of In Vivo Diagnostic Device Evaluation and Safety

SIO# K113153

0030

NOV. 29. 2011 1:44PM

NO. 1241 P. 3/25

Diagnostic Ultrasound Indications for Use Form

System

Transducer

Model:

39C00EA

S10(K) Number(s)

K13153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal							P	Note 2
Abdominal	P	P						
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic							P	Note 2
Pediatric	P	P						
Small organ (specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-rectal								
Trans-esoph (non-Card)							P	Note 2
Musculo-skeletal Conventional	P	P						
Musculo-skeletal Superficial								
Intravascular							P	Note 2
Cardiac Adult	P	P						
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph (Cardiac)								
Intra-Cardiac							P	Note 2
Peripheral Vascular	P	P						
Other (specify)***								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-brust, thyroid, testes.

***Other use includes Urology.

Note 1: These Harmonic Imaging. The feature does not use contrast agent.

Note 2: Biopsy Guidance

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHHL, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)

[Signature]
 (Division Sign-Off)
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

S10K K13153

0031

NOV. 29. 2011 1:44PM

HVA 1241 P. 07/14

Diagnostic Ultrasound Indications for Use Form

System

Transducer

Model:

35C508B

510(k) Number(s)

K113153

Clinical Application	Mode of Operation							Other (specify)
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	
Ophthalmic								
Fetal	N	N					N	Note 1, Note 2
Abdominal	N	N					N	Note 1, Note 2
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N					N	Note 1, Note 2
Small organ (specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-cranial								
Trans-vaginal								
Trans-rectal								
Trans-esoph (non-Card)								
Musculo-skeletal Conventional	N	N					N	Note 1, Note 2
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph (Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
Other (specify)***	N	N					N	Note 1, Note 2

N=new indication; F=previously cleared by FDA; E=added under Appendix B

Additional comments: Combined modes: B+M

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ: breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. This feature does not use contrast agents.

Note 2: Biopsy Guidance.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRE, Office of Device Evaluation (ODE)

Prescription USE (For 21 CFR 801.109)

Michael D. O'Hara
 (Division Sign-Off)
 Division of Radiological Devices
 Office of In Vivo Diagnostic Device Evaluation and Safety

STOK K113153

0032

NOV. 29. 2011 1:44PM

NOV 14/11 1: 0/14

Diagnostic Ultrasound Indications for Use Form

System

Transducer

Model:

65EC108B

510(k) Number(s)

K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Tenai	N	N					N	Note 2
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Podiatric								
Small organs (specify)**								
Neonatal Cephalic	N	N					N	Note 2
Adult Cephalic								
Trans-rectal	N	N					N	Note 2
Trans-vaginal	N	N					N	Note 2
Trans-metrial								
Trans-ecph (non-Card)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-ecph (Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
Other (specify)***	N	N					N	Note 2

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organs: breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRE, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)

Susan D. Goldstein-Falk
 (Device Sign-Off)
 Division of Radiologic Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113153

0034

NOV. 29. 2011 1:44PM

NOV. 12/11 P. 3/29

Diagnostic Ultrasound Indications for Use Form

System

Transducer

Model:

GEEL602A

S10(k) Number(s)

K11315

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal	P	P					P	None 2
Trans-vaginal								
Trans-urethral								
Trans-esoph (non-Card.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph (Cardiac)								
Imm-Cardiac								
Peripheral Vascular								
Other(specify)***	P	P					P	None 2

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments-Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testis.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The system does not use contrast agents.

Note 2: Biopsy Guidance

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Consent of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

Susan D. Goldstein-Falk
 (Division Sign-Off)
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

S10K K11315

0035

NOV. 29. 2011 1:45PM

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Diagnostic Ultrasound Indications for the Form

System

Transducer

Model:

75L385B

510(k) Number(s)

K113153

Clinical Application	Mode of Operation							Other (specify)
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	
Ophthalmic								
Fetal							N	Note 2
Abdominal	N	N						
Intraoperative (specify)**								
Intraoperative (Neuro)								
Laparoscopy							N	Note 2
Pediatric	N	N					N	Note 2
Small organ (specify)***	N	N					N	Note 2
Neonatal Cephalic	N	N						
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph (non-Card)							N	Note 2
Musculo-skeletal Conventional	N	N					N	Note 2
Musculo-skeletal Superficial	N	N						
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph (Cardiac)								
Intra-Cardiac							N	Note 2
Peripheral Vascular	N	N						
Other (specify)***								

N=new indication; P=previously cleared by FDA; U=added under Appendix B

Additional comments: Combined modes: B+M.

**Intraoperative includes abdominal, thoracic, and vascular.

***Small organ includes thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The scanner does not use contrast agents.

Note 2: Ectopy Guidance

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Consent of CDRH, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)

[Signature]
 (Division Sign-Off)
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

610K K113153

0036

Diagnostic Ultrasound Indications for Use Form

System

Transducer

Model:

75L53EA

SIO(k) Number(s)

K13153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P					P	Note 2
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P					P	Note 2
Small organ (specify)**	P	P					P	Note 2
Neonatal Cephalic	P	P					P	Note 2
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph (non-Card)								
Musculo-skeletal Conventional	P	P					P	Note 2
Musculo-skeletal Superficial	P	P					P	Note 2
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph (Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P					P	Note 2
Other (specify)***								

N=new indication; P=previously cleared by FDA; B=added under Appendix E

Additional comment: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ=breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 901.109)

[Signature]
 Director (Sign-Off)
 Division of Radiological Devices
 Office of In Vivo Diagnostic Device Evaluation and Safety

DICK K13153

0037

Diagnostic Ultrasound Indications for Use Form

System

Transducer

Model

7SLT3R2A

510(k) Number(s)

K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P					P	Note 2
Intraoperative (specify)*	P	P					P	Note 2
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P					P	Note 2
Small organ (specify)**	P	P					P	Note 2
Neonatal Cephalic	P	P					P	Note 2
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph (non-Card)								
Musculo-skeletal Conventional	P	P					P	Note 2
Musculo-skeletal Superficial	P	P					P	Note 2
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph (Cardiac)								
Intra-Cardiac								
Periphereal Vascular	P	P					P	Note 2
Other (specify)***								

N=new indication; P=previously cleared by FDA; B=added under Appendix E

Additional comments: Combined modes: B+M

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The system does not use contrast agents.

Note 2: Biopsy Guidance

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRE, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 901.109)

[Signature]
 (Please Sign-Off)
 Division of Radiological Devices
 Office of In Vitro Diagnostic Devices Evaluation and Safety

610K

K113153

0038

NOV. 29. 2011 1:53PM

NO. 124/ P. 13/24

Diagnostic Ultrasound Indications for Use Form

System

Transducer

Model:

DP-30

S10(k) Number(s)

K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic							N	Note 1, Note 2
Fetal	N	N					N	Note 1, Note 2
Abdominal	N	N					N	Note 2
Intraoperative (specify)*	N	N						
Intraoperative (Neuro)								
Laparoscopic							N	Note 1, Note 2
Pediatric	N	N					N	Note 2
Small organ (specify)**	N	N					N	Note 2
Neonatal Cephalic	N	N					N	Note 2
Axial Cephalic	N	N					N	Note 2
Trans-rectal	N	N					N	Note 2
Trans-vaginal	N	N					N	Note 2
Trans-urethral								
Trans-esoph (non-Card)							N	Note 1, Note 2
Musculo-skeletal	N	N					N	Note 2
Conventional								
Musculo-skeletal Superficial	N	N						
Intravascular							N	Note 2
Cardiac Adult	N	N					N	Note 2
Cardiac Pediatric	N	N						
Intravascular (Cardiac)								
Trans-esoph (Cardiac)								
Intra-Cardiac							N	Note 2
Peripheral vascular	N	N					N	Note 1, Note 2
Other (specify)***	N	N						

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ: breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The device does not use contrast agents.

Note 2: Biopsy Guidance

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Consentance of CDER, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR
901.109)

[Signature]
(User Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

S10K

K113153

0039

NOV. 29. 2011 1:53PM

NO. 1247 P. 14/24

Diagnostic Ultrasound Indications for Use Form

System: _____

Transducer: _____

Model: _____

35C205A

S10(K) Number(s): _____

K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P					P	Note 2
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P					P	Note 2
Small organ (specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-mammary								
Trans-esoph (non-Card.)								
Musculo-skeletal Conventional	P	P					P	Note 2
Musculo-skeletal Superficial								
Intra-vascular								
Cardiac Adult	P	P					P	Note 2
Cardiac Pediatric								
Intra-vascular (Cardiac)								
Trans-esoph (Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P					P	Note 2
Other (specify)***								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. This feature does not use contrast agents.

Note 2: Biopsy Guidance

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDER, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)

[Signature]
 (Division Eight-01)
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

S10K

K113153

0040

NOV. 29. 2011 1:53PM

NO. 1247 P. 12/19

Diagnostic Ultrasound Indications for Use Form

System

Transducer

Model

35C502A

510(k) Number(s)

K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	P	P					P	Note 1, Note 2
Abdominal	P	P					P	Note 1, Note 2
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P					P	Note 1, Note 2
Small organ (specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph (non-Card.)								
Musculo-skeletal Conventional	P	P					P	Note 1, Note 2
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph (Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
Other (specify)***	P	P					P	Note 1, Note 2

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. This feature does not use contrast agents.

Note 2: Biopsy Guidance

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription USE (Per 21 CFR 801.109)

[Signature]
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 Office of In Vitro Diagnostic Device Evaluation and Safety

510K: K113153

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Diagnostic Ultrasound Indications for Use Form
Transducer

System

Model:

S10(k) Number(s)

63C15EA

K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P					P	Note 2
Intraoperative (specify)**								
Intraoperative (Neuro)								
Laparoscopy							P	Note 1
Pediatric	P	P						
Small organ (specify)**							P	Note 2
Neonatal Cephalic	P	P					P	Note 2
Adult Cephalic	P	P						
Trans-rectal								
Trans-vaginal								
Trans-nuchal								
Trans-esoph (non-Card)							P	Note 2
Musculo-skeletal Conventional	P	P						
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult							P	Note 2
Cardiac Pediatric	P	P						
Intravascular (Cardiac)								
Trans-esoph (Cardiac)								
Intra-Cardiac							P	Note 2
Peripheral Vascular	P	P						
Other (specify)***								

New indication; P-previously cleared by FDA, E-added under Appendix E

Additional comments: Combined modes: B+M

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Bypass Guidelines

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Concurrence of CDRE, Office of Device Evaluation (ODE)

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Diagnostic Ultrasound Indications for Use Forst

System

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Model:

65BC10EA

510(k) Number(s)

K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	P	P					P	Note 2
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ (specify)**								
Neonatal Cephalic	P	P					P	Note 2
Adult Cephalic								
Trans-cervical	P	P					P	Note 2
Trans-vaginal	P	P					P	Note 2
Trans-urethral								
Trans-esoph (non-Card.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph (Cardiac)								
Intra-Cardiac								
Peripheral Vascular							P	Note 2
Other (specify)***	P	P						

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Diagnostic Ultrasound Indications for Use Form

System

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Model:

65BL602A

510(k) Number(s)

K113158

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ (specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal	P	P					P	Note 2
Trans-vaginal								
Trans-urethral								
Trans-esoph (non-Card)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph (Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
Other (specify)***	P	P					P	Note 2

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Diagnostic Ultrasound Indications for Use Form

System

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Model:

64EB105A

510(k) Number(s)

K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopy								
Pediatric								
Small organ (specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal	N	N					N	Note 2
Trans-vaginal								
Trans-urethral								
Trans-esoph (non-Card)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph (Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
Other (specify)***	N	N					N	Note 2

N=new indication; P=previously cleared by FDA; B=added under Appendix E

Additional comments: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Diagnostic Ultrasound Indications for Use Form

System

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Model:

65EC10HD

SIO(K) Number(s)

15113/53

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Optimalistic								
Real	N	N					N	Note 2
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal	N	N					N	Note 2
Trans-rectal								
Trans-esoph(non-Card.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Pericardial Vascular								
Other (specify)***								

N=new Indication; F=previously claimed by FDA; B=added under Appendix E

Additional comments: Combined modes: B+M

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testis.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Diagnostic Ultrasound Indications for Use Form

System

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Model:

79L382A

510(k) Number(s)

K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P					P	Note 2
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Podiatric	P	P					P	Note 3
Small organ(specify)**	P	P					P	Note 2
Neonatal Cephalic	P	P					P	Note 2
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-rectal								
Trans-esoph(ana-Card.)								
Musculo-skeletal Conventional	P	P					P	Note 2
Musculo-skeletal Superficial	P	P					P	Note 2
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph(Cardiac)								
Intra-Cardiac								
Pericardial Vascular	P	P					P	Note 2
Other (specify)***								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testis.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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 Office of In Vitro Diagnostic Device Evaluation and Safety

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Diagnostic Ultrasound Indications for Use Form

System

Transducer

Model:

75L335A

510(K) Number(s)

K113153

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal							P	Note 2
Abdominal	P	P						
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic							P	Note 2
Pediatric	P	P					P	Note 2
Small organ (specify)**	P	P					P	Note 2
Neonatal Cephalic	P	P						
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph (non-Card)								
Musculo-skeletal Conventional	P	P					P	Note 2
Musculo-skeletal Superficial	P	P					P	Note 2
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph (Cardiac)								
Intra-Cardiac							P	Note 2
Peripheral Vascular	P	P						
Other (specify)***								

N=new indication; P=previously cleared by FDA; R=added under Appendix E

Additional comments: Combined modes: B+M

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ: breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Susan O. Goldstein-Falk
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 Division of Neurological Devices
 Office of In Vivo Diagnostic Device Evaluation and Safety

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Diagnostic Ultrasound Indications for Use Form

System

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Model:

75LTS6RA

S100(s) Number(s)

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Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Optimistic								
Fetal								
Abdominal	P	P					P	Note 2
Intraoperative (specify)*	P	P					P	Note 2
Intraoperative (Neuro)								
Laparoscopic								
Podiatric	P	P					P	Note 2
Small organ(specify)**	P	P					P	Note 2
Neonatal Cephalic	P	P					P	Note 2
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional	P	P					P	Note 2
Musculo-skeletal Superficial	P	P					P	Note 2
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph. (Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P					P	Note 2
Other (specify)***								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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 Division of Radiological Devices
 Office of In vitro Diagnostic Device Evaluation and Safety
 Date: K113153

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NO. 1241 P. 23/24

Diagnostic Ultrasound Indications for Use Form

System

Transducer

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Model:

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510(k) Number(s)

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Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	P	P					P	Note 2
Intraoperative (specify)*	P	P					P	Note 2
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P					P	Note 2
Small organ (specify)**	P	P					P	Note 2
Neonatal Cephalic	P	P					P	Note 2
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-rectal								
Trans-esoph (non-Card)								
Musculo-skeletal Conventional	P	P					P	Note 2
Musculo-skeletal Superficial	P	P					P	Note 2
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph (Cardiac)								
Intra-Cardiac								
Peripheral Vascular	P	P					P	Note 2
Other (specify)***								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Diagnostic Ultrasound Indications for Use Form

System

Transducer

Model:

10L24BA

S10(s) Number(s)

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Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ(specify)**	N	N					N	Note 2
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph (neo-Card.)								
Musculo-skeletal Conventional	N	N					N	Note 2
Musculo-skeletal Superficial	N	N					N	Note 2
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	N	N					N	Note 2
Other (specify)***								

N=new indication; P=previously cleared by FDA; B=added under Appendix E.

Additional comments: Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ=breast, thyroid, testes.

***Other use includes Urology.

Note 1: Trans Esophageal Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Diagnostic Ultrasound Indications for Use Form

System

Transducer

Model:

10L245A

510(k) Number(s)

K113153

Clinical Application	Mode of Operation							
	B	M	FWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ(specify)**	N	N					N	Note 2
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph (non-Card.)							N	Note 2
Musculo-skeletal Conventional	N	N					N	Note 2
Musculo-skeletal Superficial	N	N						
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph. (Cardiac)								
Intra-Cardiac							N	Note 2
Peripheral Vascular	N	N						
Other (specify)***								

N=new indication; P=previously cleared by FDA; B=added under Appendix B

Additional comments: Combined modes: B+M

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

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Concurrence of CDRL Office of Device Evaluation(ODE)

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